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NIH Policy Update: Balancing Sex in Animal and Cell Studies

Over the last couple decades, we have gathered an increasing amount of information about how men and women respond differently to medications and medical interventions and have different risks and responses to a multitude of diseases. This increased awareness comes partially as a result of changes in National Institutes of Health (NIH)-funded clinical research included in the NIH Revitalization Act of 1993, which required women and minorities be included in research. Yet, while women now represent just over half of the participants in NIH-funded clinical research, there has not been a parallel change in experimental design and analyses in cell and animal research. This is evidenced through a study, conducted by Northwestern University's Dr. Melina Kibbe and Dr. Teresa Woodruff, clearly demonstrating that sex disparity exists in biomedical surgical research. The article reports that astonishingly, of the 618 publications that cited using animals and/or cells, only 13 included both males and females. Furthermore the authors state, "for publications on female-prevalent disorder, such as thyroid and cardiovascular disease, in which one would expect a larger number of publications studying females, only 12% studied females or both sexes."¹ Such an

overdependence on male animals/cells in preclinical research not only disguises relevant sex differences that can guide clinical studies, the inadequate inclusion of female animals/cells in experiments may contribute to the problem of irreproducibility in other preclinical biomedical research ².

Recognizing the significant consequences of dismissing such a fundamental variable, the NIH recently issued a [notice](#) highlighting its expectation that scientists account for the potential role of sex as a biological variable in vertebrate animal and human studies. Policy updates take effect for all NIH grant applications submitted on/after the January 25, 2016 deadline, requiring applicants to report their plans for including both male and female animals/cells in preclinical studies. If sex-specific inclusion is unjustified, applicants must now explain the intended exception.

Research administrators can help support the process of a successful submission by communicating these changes with their faculty. In addition to changed language in the NIH grant proposal, researchers should also plan for providing more detailed information in animal study protocols when submitting for Institutional Animal Care and Use Committee (IACUC) approval of NIH-funded protocols. "The new guidance requires a more formalized process to include documentation of congruency to assure procedures in the grant submission are the same as those proposed in the study protocol," reports Mandy Kozlowski, Director of Northwestern's IACUC Office. "The variable of sex will be captured in the grant's aim, significance, and experimental design, however it must also be addressed in the animal study protocol in order to receive the IACUC approval letter for submission to the NIH."

Any questions about anticipated changes in an animal study protocol can be directed to the IACUC Office at 312-503-0112. Additionally, Northwestern's [Office for Sponsored Research website](#) links to several resources and frequently asked questions (FAQs) regarding topics such as reproducibility of data, rigor and transparency in research and consideration of relevant biological variables, such sex.

¹ Yoon, D.Y., Mansukhani, N.A., Stubbs, V.C., Helenowski, I.B., Woodruff, T.K., & Kibbe, M.R. (2014). Sex bias exists in basic science and translational surgical research. *Surgery*, 156(3), 508-516.

² Clayton, J.A., & Collins, F.A. (2014). Policy: NIH to balance sex in cell and animal studies. *Nature*, 509(7500), 282-283.

Research Administration Training Seminar

This four-session seminar is geared toward research administrators, staff involved in research administration, and anyone who wants to learn about Northwestern's research administration process, policies, and procedures. The seminar serves as an introduction to Northwestern's research enterprise and the extensive systems involved. It is a great networking and educational opportunity for staff new to research or experienced staff who would like a refresher in certain areas. Representatives from offices throughout Northwestern will be on hand to present and answer questions.

The next seminar will take place April 19th, 22nd, 26th and 28th on the Evanston campus from 9:00am-12:30pm (Chambers Hall, lower-level auditorium).

Registration can now be completed through Northwestern University's new training management system, Learn@Northwestern. Simply [log-in](#) using your NetID and password, then use the search tool in the top right-hand corner to find the Research Administration Training Seminar class. When you select "enroll," you will be registered for all four days of the seminar. If you experience difficulties registering or have any questions, please email bethirwin@northwestern.edu for support.

QUOTE CORNER

"You ask me what forces me to speak a strange thing; my conscience."

-Victor Hugo,

Les Misérables

COI Update: What You Need to Know!

Effective February 15, 2016, a revised [Conflict of Interest \(COI\) in Research Policy](#) has been released to coincide with the launch of Northwestern's new COI system, eDisclosure. "The new policy responds to the Uniform Guidance and now covers all federal and industry sponsored research," explains Kate Cosgrove Booth, Senior Compliance Analyst in the NUCOI Office. "It will help simplify the disclosure process at application time, and eliminate the question and judgement of whether or not COI disclosure requirements apply to a particular sponsored project: the new policy and process applies to all research sponsored by federal or industry sponsors." The policy also continues to apply to research sponsored by other organizations not captured in the federal and industry categories (e.g., some foundations, etc.) that have specific COI requirements. Additionally, the new policy applies to any research involving human research participants, regardless of the funding source.

This policy change impacts how research administrators navigate the COI compliance verification process, particularly administrators working with research involving human research participants. Research administrators should use the new "[Compliance Page](#)" in eDisclosure to verify compliance, as applicable, at proposal time and award time. Administrators that support Institutional Review Board (IRB) protocol submissions should take note that under the revised *COI in Research Policy*, anyone named as a Principal Investigator or Co-Investigator on an IRB protocol must have a disclosure on file in eDisclosure; the question regarding investigators' related financial interests will no longer be asked in the eIRB protocol application. By streamlining the disclosure process, there is now one point of disclosure each person makes on their own behalf, and one disclosure record that can be applied to and reviewed in the context of all bodies of research activity in which a person is engaged.

A COI in research is a situation in which an individual's external financial interests or relationships relate to and could bias or compromise, or have the appearance of biasing or compromising, an individual's judgement, objectivity, or decision-making with respect to research design, conduct, or reporting. The relation, even potential or perceived relation, of external interests and relationships to research activities needs to be assessed. Examples of financial interests or relationships that could present COIs in research include an investigator's intellectual property interests in a product, technology, or method being evaluated in Northwestern research, faculty start-up companies involved in University research, and/or consulting relationships with entities sponsoring or providing products being evaluated in Northwestern research. "COIs should not be viewed negatively!" exclaims Julia Campbell, Director of NUCOI. "Our research community is innovative, entrepreneurial, and they are experts in their respective fields; they are expected and encouraged to engage in outside activities and relationships. We just have to ensure that financial interests and relationships that relate to Northwestern activities, such as research, are known. Northwestern has an obligation to ensure that any actual or potential impacts of such financial relationships and interests on research integrity and/or objectivity are assessed and managed."

For more detailed information on Northwestern's conflict of interest program and the updated *COI in Research Policy*, visit the [NUCOI website](#).



Did You Know?

NIH will soon be requiring applicants to use new FORMS-D for applications with due dates on or after May 25, 2016. The choice of forms is determined by the actual due dates listed in the funding opportunity announcement, not the date you submit your application. View the [official announcement](#) for more details about what to expect moving forward.

Did you know that research misconduct (falsification, fabrication or plagiarism) can be found in draft documents (e.g., draft manuscripts and proposals), lab presentations and lab notebooks? The research need not be published to have a concern of potential research misconduct. Check out ORI's website for more information about the [Policy and Procedures for Reviewing Alleged Research Misconduct](#).

The Office for Sponsored Research (OSR) recently launched a web-based training component known as Sponsored Project Online Training (SPOT). Visit the training section on [OSR's website](#) to view the new mini-courses, microlearning modules, and OSR Live! Presentations.

Introducing Denise (Dee) Roe

1. What is your title at Northwestern?

Executive Director, IRB Office

2. What does that mean?

I have a role to facilitate relationships and to help navigate the complex regulatory environment related to human research. The IRB can foster positive and effective relationships through open communication and transparency. What I hope I can do is bring all of my experiences to the table in a way that can be beneficial to the University and community, to propel research forward in a meaningful way.

3. What is one thing you want people to know about what you do here?

While the IRB serves as the cornerstone for the human research protection program, an effective HRPP is much broader. I see it as a partnership, where everyone involved in the conduct and administration of research understand our role in designing, implementing and conducting human research that assures the highest level of protections and respect of our research participants/subjects.

4. How long have you been at Northwestern?

8 weeks



5. What did you do before you came to Northwestern?

I was the director of research oversight and administration at Spectrum Health System in Michigan.

6. Where is your home town?

Holland, MI

7. What is your favorite ice cream flavor?

Blue Moon

8. What is your favorite thing to do outside of work?

I love to travel, but more than anything I love going to museums and parks.

9. What is Chicago event are you most looking forward to experiencing?

Movies in the Park or the One of a Kind Show

One Step Closer to Accreditation

Northwestern University has recently made great strides in its goal of earning accreditation through the Association for Accreditation of Human Research Protection Programs (AAHRPP). The primary purpose of having AAHRPP accreditation is to strengthen protections for research participants, while also continuing to build the public's trust and confidence in Northwestern's research enterprise. Moreover, having this accreditation demonstrates that the University follows exceptional standards for ethics, quality, and protections for humans participating in research. By seeking accreditation, Northwestern joins more than 60% of U.S. research-intensive universities that are either currently accredited through AAHRPP or have begun the process.

There are several steps in the accreditation process, the first of which Northwestern completed in December 2015, by preparing and submitting a comprehensive application to AAHRPP, including an organizational overview, Institutional Review Board (IRB) policies, an intensive human research protection program assessment, and several hundred pages of supporting documentation. Once Northwestern receives and then replies to any follow-up requests from AAHRPP, the next stage in the process will be an on-site evaluation that will include interviews with organizational officials, investigators and regulatory or research coordinators, across both the Chicago and Evanston campuses. These interviews are designed to determine how integrated and collaborative the human research protection program is. Prior to the site visit, which is expected to occur in Fall 2016, the IRB will provide AAHRPP lists of all current studies and investigators, any of whom may be selected for the interviews. Finally, the application will be reviewed at a December 2016 AAHRPP counsel of accreditation meeting where Northwestern's accreditation status will be determined.

Dee Roe, IRB Office Executive Director, will be speaking about the AAHRPP site visit at the March 18, 2016 Advisory Council for Clinical Research (ACCR) [Lecture](#). Stay tuned for more information about preparations for the site visit and the status of Northwestern's AAHRPP accreditation process!

No Tolerance for Harassment in Science

Multiple cases of sexual harassment by renowned U.S. scientists have recently captured national attention and key government agencies are now actively working to address the problem. U.S. Representative Jackie Speier's (D-CA) recent statement, made on the House floor in reference to a 2004 harassment investigation at the University of Arizona involving astronomy professor Timothy Slater, perfectly highlights the issue. "It's time to stop pretending sexual harassment in science happened a long time ago in a galaxy far, far away."

Speier is drafting legislation that will require universities to communicate information about faculty members who violated sexual harassment rules when they transfer to another institution. Citing a report compiled by the University of Arizona which concluded Slater had violated campus policies on sexual harassment, including allegations of trips to strip clubs and sexual jokes, Speier argues that Slater's case exemplifies how "some universities protect predatory professors with slaps on the wrist and secrecy," since he went on to continue his career at the University of Wyoming in Laramie despite the findings.

More recent cases that highlight this serious issue involve the October 2015 resignation of Geoffrey Marcy, a University of California at Berkeley scientist who announced his retirement within days of the public outcry for not receiving harsher penalties after he was found guilty of violating campus harassment policies. Perhaps having learned from Berkeley's example, the University of California Institute of Technology (Caltech) temporarily suspended, without pay, faculty member Christian Ott in January 2016, after findings that he committed gender-based harassment against two graduate students.

Government funding agencies are also taking a strong stance against institutions that do not appropriately respond to harassment. In a January 25, 2016 [press statement](#), the National Science Foundation (NSF) detailed its commitment to preventing and dealing with gender-based discrimination in science. Calling on colleges and universities that receive NSF grant support, the agency warned that it may terminate funding to institutions found by the Departments of Justice and Education to be in non-compliance with Title IX federal regulations that prohibit discrimination on the basis of sex in any federally funded education program or activity. According to the statement, "not only is a discrimination-free environment the right setting for all people, it also fosters important learning, mentoring and research that are imperative to the advancement of science." Similarly, NASA administrator Charles Bolden released a [letter](#) on January 15, 2016 firmly denouncing harassment and urging grantee institutions to review current policies and procedures for addressing allegations of harassment and misconduct.

These recent announcements from the federal agencies are designed to enforce zero tolerance for harassment in science with clear actions, including research sanctions, for non-compliance. Northwestern University has many policies to maintain a safe and healthy campus environment. More information about these policies, or where to go for help if you, or someone you know, has been sexually harassed can be found online with the [Sexual Harassment Prevention Office](#).



EthicsPoint is a third party vendor that allows you to confidentially raise ethical concerns, ask questions, and/or report activities that may involve misconduct or violations of Northwestern University policy.

[For more information visit the website here.](#)

ORI MISSION

Identifying compliance risks in our research practices and communicating those risks to the research community;

Partnering with the research community in innovative and effective ways to minimize and manage research risks;

Educating the research community with respect to appropriate business practices related to the conduct of research at Northwestern University; and

Monitoring and correcting non-compliance in accordance with University and federal guidelines.

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